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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,111	10/25/96	ROREGER	M 1408/LTS-8/9

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HM42/0309

EXAMINER

WEBMAN, E

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

03/09/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

48/737111

Applicant(s)

R O R E G E R

Examiner

WEBMAN

Group Art Unit

1502

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/27/97.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 16-30 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16-30 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 16-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16, 17, 22, 25 'DIFFERENT' is vague; what molecular weight distribution, active substances and forms?

In claim 18 'at least one' is indefinite. Only one member of a Markush group should be chosen. It is suggested that 'and mixtures thereof' be made the last member.

In claim 24 'influenced and controlled' is vague; how?

In claim 21 'small' is vague; what length?

In claim 26 'and' is vague; does ~~the~~ 'erosion' follow the process of 'DISSOLUTION OR SWELLING'?

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luck et al. in view of Wallace et al.

Luck et al. teach a matrix of protein and drug (Abstract). Delayed release with adjuvants is specified (column 4, lines 13-19). Collagen is specified (column 3, lines 24-27). pH regulators are specified (column 5, lines 43-45). C^utan^efous treatment is disclosed (column 6, line 19). Injections are further specified (column 6, lines 47-48).

Wallace et al. teach an acid insoluble collagen powder which is chemically pure (column 11, line 17 - column 12, line 7).

It would have been obvious to use the collagen of Wallace et al. in the invention of Luck et al. to achieve the beneficial effect of chemically pure collagen, devoid of any impurities which could lead to an immune response.

As to the claimed mixtures of different molecular weights, Wallace et al. teach mixtures of collagen batches digested with trypsin ^{at} ~~at~~ different lengths of time ₁ ~~1~~ (column 12, lines 8-30). It is argued that such collagen batches will have different molecular weights in view of the differing digestion times.

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Applicant argues that there is no teaching of different molecular weight distributions or the use thereof. However, a method of the use of such distributions is not claimed. Such distributions are ^{inherent}~~instant~~ in the Wallace et al. composition. Further, motivation to combine is provided.

The disclosure is objected to because of the following informalities:

On page 2, line 6 '4409332' appears to be incorrect. See reference AF on PTO 1449.

Appropriate correction is required.

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-³⁵⁹²~~5408~~.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)

¹²³⁵
308-~~2351~~.

WEBMAN; aco

February 17, 1998



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500